REMARKS

Introductory Comments

Claims 45-48 were examined in the Office Action under reply and stand rejected under 35 U.S.C. §102(e) and under the judicially created doctrine of obviousness-type double patenting. These rejections are believed to be overcome for reasons discussed below.

Applicants request that withdrawn process claims that depend from or otherwise include all the limitations of allowable product claims be rejoined in accordance with the provisions of MPEP §821.04.

Overview of the Foregoing Amendments

The specification has been amended to update the priority information. Specifically, the patent number corresponding to grandparent application serial no. 09/698,874, 6,562,346, has been added.

Claim 45 has been amended to recite that the NS3 polypeptide is a "native NS3" polypeptide. Support for this amendment can be found throughout the specification at, *inter alia*, page 5, lines 4-14.

New claims 63-65 have been added and pertain to compositions. Support for the new claims can be found throughout the specification at, e.g., page 24, lines 9-12; and page 25, lines 3-4.

Rejections

The Office Action states that the subject matter of claims 45-48 is not entitled to the benefit of priority of U.S. provisional application serial No. 60/161,713, filed October 27, 1999. Thus, the claims are rejected under 35 U.S.C. §102(e) as allegedly being unpatentable over U.S. Patent No. 6,986,892.

Assuming, *arguendo*, that the Office's position is correct, the currently pending claims are not believed to be anticipated by the cited art. In particular, the claims are directed to polynucleotides that encode a fusion protein consisting essentially of a **native** NS3, an NS4, an NS5a, an NS5b and a core polypeptide of an HCV. The cited art does not teach or suggest such

a protein.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 218 USPQ 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

The '892 patent does not teach or suggest fusions as claimed. Rather, the '892 patent is directed to fusions that include **mutant** non-structural polypeptides, wherein the fusions include a mutated NS3 polypeptide, an NS4 polypeptide and an NS5 polypeptide. There is no mention of preparing fusion proteins as claimed herein, that include a native NS3 polypeptide. Accordingly, the '892 patent fails to anticipate the present invention and withdrawal of this basis for rejection is respectfully requested.

Obviousness-type Double Patenting

Claims 45-48 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 and 15-18 of US. Patent No. 6,986,892. Applicants note claims 1-10 and 15-18 of the '892 patent are directed to polypeptides and polypeptide compositions, **not** polynucleotides, as claimed in the present application. The Patent Office considers polypeptide claims and polynucleotide claims patentably distinct. Indeed, the Patent Office required restriction between polypeptide and polynucleotide claims in parent application serial no. 09/698,874 in a Restriction Requirement dated July 17, 2001.

Accordingly, since polypeptides and polynculeotides are considered by the Patent Office to be patentably distinct, the obviousness-type double patenting rejection is in error and should be withdrawn.

CONCLUSION

In light of the above remarks, applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at 650-493-3400.

The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

Please direct all further written communications regarding this application to:

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